This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1 CERTIFICATE NUMBER: 42-F-0007
CUSTOMER NUMBER: 1588

FORM APPROVED
OMB NO. 0579-0036

Nat'L Ani Dis Center
P.O. Box 70
2300 Dayton Ave
Ames, IA 50010

Telephone: (515) -663-7200

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters		10	9	4	23
8. Rabbits		12	25		37
9. Non-human Primates					
10. Sheep		254			254
11. Pigs		500	118	300	918
12. Other Farm Animals					
Cattle		201	65	34	300
13. Other Animals					
Bison		64			64
White Tail Deer		262	10	8	280

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and apr Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
(b)(6),(b)(7)(c)	(b)(6),(b)(7)(c)	11/3/05

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

2006

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No. 0190-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
42-F-0007

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and address, as registered with USDA, include Zip Code)*

Natl Ani Dis Center
P.O. Box 70
2300 Dayton Ave.
Ames, IA 50010

Phone: (515) 663-7200

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations 12. &/OR 13. Other *(List by species)*	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
12. Goats		30			30
Horses		2			2
13. Fallow Deer		10			10
Elk		26			26
Raccoons		36			36

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2). Each principal investigator has considered alternatives to painful procedures.

3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
	(b)(6),(b)(7)(c)	

APHIS FORM 7023A

Registration # 42-F-007
National Animal Disease Center

Column E Explanation:
Studies include 364 animals: Cattle, Swine, Whitetail Deer, Hamsters, Turkey

Cattle:

1. The objective of the study is to study the immune function and pathogenesis during early and late infection. The study also provides opportunities with which to evaluate diagnostic tools for the detection of Paratuberculosis. A search of Pubmed (keywords – Johne's disease, diarrhea treatment, pain and distress) did not yield any alternative to relief of painful or distressful symptoms of the disease.
2. The use of drugs would change the natural course of disease progression and alter the interpretation of the results.

1. The objective of the study is to identify virulence markers associated with different pathogenic strains. An associated objective is to determine the disease syndromes associated with the different BVDV strains. It is necessary that the disease, even with distressful symptoms be allowed to be manifest.
2. The use of any drugs to alter the distress would alter the comparative evaluation of the different strains.

Swine:

1. The objective of the study is to identify swine that exhibit differences in Salmonella shedding patterns and characterize the alterations in gene expression between persistent shedders and non-shedders of Salmonella. The validity of the study results requires that the infectious disease induced by S. Typhimurium be allowed to manifest without the use of therapeutic drugs.
2. The use of antimicrobials will hinder the ability to identify swine with variations in resistance to Salmonella infection. No alternatives were found to alleviate the distress without affecting the disease expression.

1. The objective of the study is to evaluate the efficacy of commercially or experimentally-prepared Swine Influenza vaccines.
2. No literature search hits were detected that discussed alternatives for studying efficacy of SIV vaccines other than using swine infected with the desired agent and allowing the disease to manifest itself.

1. The objective of the study is to investigate the pathogenesis of a filterable agent that has been isolated and is thought to be the etiological agent for a reproductive failure disease in swine, in the field. The onset of clinical signs is necessary to judge the pathogenic effects of the challenge and to study pathogenesis of the disease.
2. Drugs that might alter the clinical signs would obscure the pathogenic effects of the challenge and thus the pathogenesis of the disease. Therefore they cannot be used.

1. The objective of the study is to study the pathogenesis of a filterable virus that has been isolated in the field. It is though to be the cause of a reproductive failure disease in swine. The manifestation of clinical disease is necessary to judge the pathogenic effects of the challenge and to study the pathogenesis of the disease.

42-F-0007

2. Drugs that might alleviate the clinical signs would obscure the pathogenic effects of the disease. No drugs were noted in the literature search that would alleviate symptoms without altering the clinical signs.

1. The objective of the study is to evaluate two types of new vaccines to overcome the current swine influenza vaccine failure in swine. Manifestations of clinical signs are required to evaluate the effects of Swine Influenza challenge virus.
2. Drug usage would mask symptoms and alter the study results.

1. The objective of this study is characterize the inate and adaptive PRRSV immune response The onset of clinical signs is necessary to judge the pathogenic effects of the challenge and to study the virus-specific immune response.
2. Drugs that might alleviate the clinical signs could obscure the pathogenic effects. No such drug regimen was found in the literature.

1. The objective of this study is to evaluate the pathogenesis of Swine Influenza field isolates and the efficacy of SIV vaccines.
2. The onset of clinical signs is necessary to judge the pathogenic effects of the challenge virus and to evaluate the efficacy of the respective vaccines. No alternative to the use of swine to evaluate the effects of a virus challenge were detected.

Whitetail Deer:

1. The objective of the study is to characterize BVDV infection in whitetail deer. An associated objective is to determine if whitetail deer can serve as a reservoir of infection for cattle. A search of Pubmed did not yield alternatives to the use of whitetail deer in this study.
2. The use of any means to relieve the pain or distress of the infected animals may interfere with the natural progression of the infectious cycle which would compromise the objective of the study.

Turkeys:

1. The objective of this study is to determine if the use of vaccine with recombinant 39 kDA cross protection factor (PlpB, liproprotine) of P. Multocida will provide protective immunity against challenge. A search of Pubmed did not yield alternatives to the use of turkeys for a challenge study.
2. The use of drugs to relieve the pain or distress of the disease symptoms would alter the results of the study.

Hamsters:

1. The objective of this study is to determine the virulence through in vivo experimentation. This information is required to correlate with genetic data being collected and analyzed in the laboratory. Assessment of disease progression needs to be evaluated through observation of clinical signs.
2. Alleviating or relieving these signs will interfere with assessment. No alternative to the procedures were identified which would allow evaluation of leptospiral virulence. A literature search was conducted using CAB Abstracts and Biological Abstracts, (keywords-hamster with leptospiro, animal model, experimental model, cell culture and/or disease model.

USDA

United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

February 7, 2006

J. E. Slauter, VMO
Animal Care Western Region
2150 Centre Ave., Bldg. B, MS #3W11
Ft. Collins, Colorado 80526

Dear Dr. Slauter:

In response to your letter dated January 23, 2006, (Customer #1588, Registration #42-F-0007) requesting additional detail for the Annual Report, APHIS Form 7023, I provide the following explanations:

Column E Total: Discrepancy in number of animals:
The turkeys should not have been included in Column E. The correct total for Column E is 346.

White Tail Deer (8): Reasons use of pain and/or distress-relieving drugs interfere with study:
The study requires that the natural progression of the disease be observed. Characterization of the disease requires the observation of several parameters, including temperature, leukocyte count, and general attitude, depression, or excitement. The use of pharmaceuticals would alter the normal response to the disease as indicated below:

- Flunixin Meglumine (Banamine) would be expected to relieve the chronic pain (alter the depressive effect) and lower the temperature, thus masking the temperature changes and depression.
- Aspirin would reduce the temperature.
- Antibiotics would be expected to lower the response of the animal's immune system. This is especially critical as the viral disease studied may be expected to lower the immune system. Antibiotics are also expected to alter the leukocyte count.

Please feel free to contact me if you need additional clarification.

Sincerely,

(b)(6),(b)(7)(c)

ars

FEB 10 2006

Midwest Area • National Animal Disease Center
Director's Office
2300 Dayton Avenue • P.O. Box 70 • Ames, IA 50010
Voice: 515-663-7201 • Fax: 515-663-7677 • E-mail: rhorst@nadc.ars.usda.gov
(b)(6), (b)(7)c